A Systematic Review and Meta-Analysis of Baseline Ohip-Edent Scores

ABSTRACT

Background: OHIP-EDENT is widely used in the literature to assess Oral-Health-Related-Quality-of-Life (OHRQoL) for edentulous patients. However the normal variance and mean of the baseline OHIP scores has not been reported. It would facilitate critical appraisal of studies if we had knowledge of the normal variation and mean of baseline OHIP-EDENT scores. An established figure for baseline OHIP-EDENT, obtained from a meta-analysis, would simplify comparisons of studies and quantify variations in initial OHRQoL of the trial participants. Objectives: The aim of this study is to quantify a normal baseline value for pre-operative OHIP-EDENT scores by a systematic review and meta-analysis of the available literature. Methods: A systematic literature review was carried. 83 papers were identified that included OHIP-EDENT values. After screening and eligibility assessment, 7 papers were selected and included in the meta-analysis. Results: A meta-analysis for the 7 papers by a random-effect model yielded a mean baseline OHIP-EDENT score of 28.63 with a 95% Confidence intervals from 21.93 to 35.34. Conclusion: A pre-operative baseline OHIP-EDENT has been established by meta-analysis of published papers. This will facilitate the comparison of the initial OHRQoL of one study population to that found elsewhere in the published literature.

INTRODUCTION

UK latest Adult Dental Health Survey shows that 6% of the population are edentulous.[1] The loss of natural teeth constitutes a form of physical impairment directly related to a deterioration in the quality of life.[2] Edentulous patients can struggle with the performance of tasks such as eating and speaking.[3] Being edentulous affects facial aesthetics due to atrophy of dental support structures[4] and issues regarding general appearance are a common concern expressed by such patients.[5] The conventional treatment of edentulous patients is the provision of a complete dentures[5] which has been shown to significantly impact on oral health-related quality of life.[6] The assessment of patient outcomes in clinical trials has often been achieved by a validated tool for patient reported oral health-related quality of life.

Oral Health-Related Quality of Life (OHRQoL) is a term which has been defined and developed over a number of years. Previously, when considering the general health and well-being of the patient, the oral cavity had been isolated from the rest of the body.[7] The concept of 'oral health-related quality of life' was established to counter this trend. The term was initially coined by Gift and Redford[8] so as to allow measurements of the functional, social and psychological impact of oral conditions and diseases[9] Prior to this, it was termed under socio-dental indicators or subjective oral health indicators[10] but the term 'quality of life' was preferred by Locker and Allen as it was defined as being broader than merely 'health' or 'disease'.[10] Many definitions have been offered,

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Authors

Dr. Jabir M J Duale *
(BChD, MChD, BSc)

Dr. Yahya A Patel §
(BChD, MChD, BSc)

Dr. Jianhua Wu ‡
(BSc (Hons), PhD)

Dr. T Paul Hyde ‡
(BChD, PhD, DGDP RCS (Eng), MGDS RCS (Eng), FHEA)

Address for Correspondence

Dr. T Paul Hyde ‡

Email: t.p.hyde@leeds.ac.uk

* *General Dental Practitioner, 62 Church Street, Littleborough*

§ *General Dental Practitioner, Elizabeth house, Bradley street*

‡ *University of Leeds*

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however the definition, based on WHO model, is perhaps the one that is most accurate and informative; it is given by Locker and Allen[10] who define Oral Health-Related Quality of Life (OHRQoL) as "the impact of oral disorders on aspects of everyday life that are important to patients and persons, with those impacts being of sufficient magnitude, whether in terms of severity, frequency or duration, to affect an individual's perception of their life overall."[10]

Oral healthcare professionals have been trained in the diagnosis and clinical management of oral conditions. However, diagnosing a condition only reflects the end-stage of the condition but not on the impact (whether physical or psychological) this may have had on the individual patient.[11] This becomes particularly evident when considering the difference demonstrated between the opinion of the treating professional and the perceived OHRQoL of the patient themselves.[12] It is the patients' perception that is crucial when considering OHRQoL. Tools, including the Oral Health Impact Profile (OHIP), have been developed to measure patient reported OHRQoL. These OHRQoL measures have been used for audits, clinical trials, cost-utility analysis[11] and allocation of resources.[13]

Awad *et al*. report the use of such tools in prosthodontic dental treatment is justified as they have been shown to be sensitive enough to record clinically significant differences between different prosthodontic treatments.[14] In contrast, other outcomes for prosthodontic treatment cannot be assessed reliably enough by clinical measurements alone.[15]

Accurately assessing quality of life poses a multitude of challenges due to it being inherently linked with an individual's expectations[16] and how unique it is to an individual.[17] Compounded to this, it is a 'dynamic construct' and therefore subject to change over time.[18]

Oral Health Impact Profile (OHIP) was originally constructed on the basis of the WHO classification of impairments, disability and handicap (Slade and Spencer, 1994). It was designed to be a measure of perceived OHRQoL, as reported on by the patient.[10] It allowed for the differentiation of issues experienced by subjects to be classed as 'internal' (i.e. issue only affects the individual) or 'interpersonal/social' (i.e. it has social consequences on the individual).[19] The main categories being assessed were dysfunction, discomfort and disability.[10]

In the preliminary construction of the questionnaire, 535 statements were recorded from semi-structured interviews with patients and then used to produce the final 49 item questionnaire. This was done to allow it to be constructed with a patient centred approach in mind.[10] This was as opposed to the questionnaire being designed by oral health care professionals and has been hailed as one of the strengths of the OHIP questionnaire.[20]

The OHIP questionnaire is regarded as the most sensitive method of assessing impact of prosthodontic treatment on OHRQoL[21] and is the most widely used instrument, having demonstrated validity and reliability.[22] It has performed well against other OHRQoL measures as Montero *et al*. concluded OHIP had shown 53% increased sensitivity when detecting unsatisfactory prosthesis compared with Oral Impacts on Daily Performance.[21]

Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT) was a tool used to measure OHRQoL as adapted by Allen and Locker[10] from the original Oral Health Impact (OHIP) questionnaire proposed by Slade and Spencer.[19] It assesses the same seven domains as the original OHIP-49 questionnaire.[23] It was designed specifically for edentulous patients with the context of prosthodontic treatment in mind.[24] The outcome variables measured by OHIP have been acknowledged as both a valid and reliable assessment tool by Slade and Spencer[19] Other studies have concluded the OHIP-EDENT as an adequate tool when measuring OHRQoL also.[25] According to Allen[10] the OHIP-EDENT measure is specific to the particular oral disease/condition and thus more likely to detect subtle changes as the statements contained within this form of questionnaire is specific to the target population.

Thus the OHIP-EDENT questionnaire has become the gold standard for reporting patient centred quality of life in edentulous patients. Translated in many languages, it has been widely used by the prosthodontic research community. The majority of Randomised Controlled Trials (RCTs) of complete dentures now include OHIP-EDENTs as either a primary or a secondary outcome. However, the study populations in each RCT are unique and direct comparisons between trails can be problematic. When critically appraising a RCT, and assessing the impact of the intervention being investigated, it would be useful to know how the initial OHRQoL of trial participants compared to the initial OHRQoL found in other trials. A systematic review and subsequent meta-analysis of baseline OHIP-EDENT scores has not been published previously; there was a clear paucity of information. The aim of this study was to evaluate and establish a baseline OHIP-EDENT score for patients prior to treatment.

The objectives were:

1. Systematic review of the studies that have included OHIP-EDENT baseline scores using parametric assessment.
2. Meta-analysis of the available data.

The Null hypothesis is that it is not possible to derive a baseline OHIP-EDENT from the available literature.

METHOD

The methodology has been modelled on guidance provided by PRISMA[26] and Cochrane Handbook for Systematic Review.[27]

In preparation for the database search a "PICOS" assessment was conducted. 'Participants' were edentate patients over the age of 18. The 'Intervention' was a OHIP EDENT questionnaire carried out as part of a clinical prosthodontic study of complete dentures. The 'Comparator' was the reported pre-operative OHIP-EDENT score. The 'Outcomes' required to be recorded were the mean, standard deviation and number of participants of the pre-operative OHIP-EDENT questionnaire. Finally the 'Study Types' looked for were Randomised Controlled Trials (RCTs), systematic reviews, cohort studies and cross sectional studies with pre-operative OHIP-EDENT score.

The specific search terms used were:

"[oral health impact profile for edentulous patients" OR "OHIP-EDENT" OR "OHIP EDENT" OR "OHIP edentulous" OR "OHIP edentate" OR "oral health impact profile" OR "OHIP-EDENT questionnaire" OR "OHIP EDENT questionnaire" OR "oral health related quality of life" OR "oral health-related quality of life" OR "OHRQoL" OR "oral health-related QoL" OR "health indices" OR "OH-QoL"] AND ["baseline" OR "pre-op" OR "pre op" OR "pre-treatment" OR "pre treatment" OR "prior to treatment" OR "pre operatively" OR "pre-operatively"] AND ["edentulous" OR "edentate" OR "toothless" OR "tooth-less" OR "edentulism"] AND ["Complete denture(s)" OR "C/C" OR "full denture(s)" OR "complete prosthesis" OR "full prosthesis" OR "complete maxillary mandibular denture(s) OR "complete upper lower denture(s)" OR "full upper lower denture(s)" OR "complete mandibular maxillary prosthesis"]

The Search Databases were: Medline (OVID) (last search 18th December 2016); Embase (last search 18th December 2016); Google Scholar (last search 20th December 2016); Cochrane Database (last search 21st December 2016);

The predetermined eligibility criteria used were:

Inclusion Criteria:

1. Studies that have used OHIP-EDENT questionnaire as a method of assessment for perceived OHRQoL prior to treatment.
2. Studies where the participant group are wholly edentate.
3. Studies that have reported OHIP-EDENT baseline scores parametrically..
4. Studies where all the participants are aged 18 or over at the time of commencement of the study
5. Studies carried out both in primary and secondary care settings.
6. Randomised Controlled Trials (RCTs), systematic reviews and cohort studies.
7. Studies published within the last 20 years (1996-2016).
8. Studies written in English.
9. Studies that have been published.

Exclusion Criteria:

1. Papers which outline a study protocol but contain no new data.
2. Studies assessing validity of OHIP-EDENT.
3. Data for the OHIP–EDENT score has been analysed non-parametrically.

The database searches were carried out and a log of all the studies returned from the search has been recorded and archived. The number of studies obtained at each stage of analysis were entered into the PRISMA 2009 flow diagram *(Figure 1)*.

Studies were identified from the searches, the duplicates were removed, the studies were screened through reading of their abstract and assessed against the pre-determined eligibility criteria, selected papers were downloaded in full and reassessed prior to inclusion in the systematic review and subsequent meta-analysis.

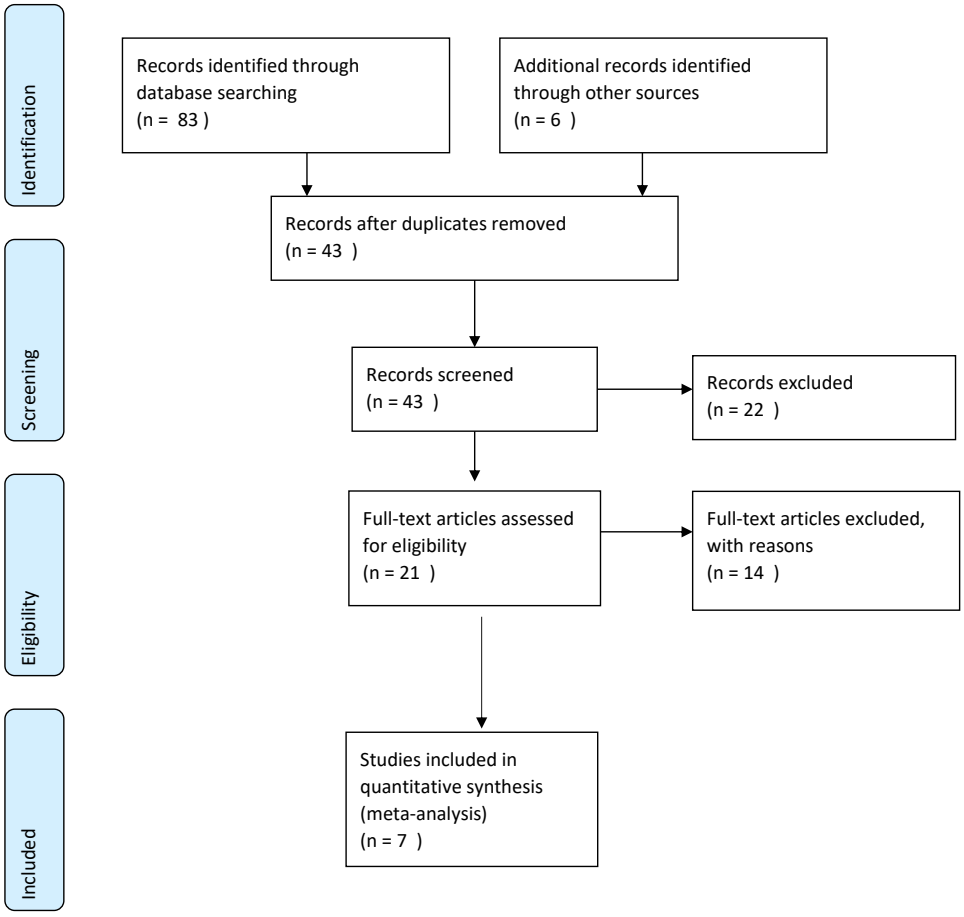

Figure 1: The PRISMA 2009 Flow Diagram showing total number of studies identified and their subsequent inclusion or exclusion for meta-analysis.

The study selection was carried out independently, by two researchers. They then discussed, compared and contrasted their short listing. Explanation of the excluded studies was documented and archived.

Data Collection Process was completed by the review team recording the following information for each study eligible for inclusion in the review: Title and author; Year of publication; Sample size; Study design; Baseline mean of the OHIP-EDENT score; standard deviation of the baseline mean OHIP-EDENT score. The data was collated in Table 1.

In order to perform the analysis of the data obtained from the studies identified by the systematic review, the journal articles were subjected to critical appraisal of their statistical methodology prior to inclusion in the meta-analysis. Different studies analyse their OHIP-EDENT scores differently, following either a parametric or non-parametric analysis model. For the purposes of this the meta-analysis, only those studies that assessed OHIP-EDENT parametrically were included.

RESULTS

After an electronic database search had been carried out, a total of 43 journal articles were identified once duplicates had been removed. Screening of the 43 journal articles took place by reading the abstracts and a further 22 journal articles were excluded during screening process as they did not fit the inclusion/exclusion criteria. A total of 21 studies were allocated study IDs and the full articles were downloaded to be re-assessed for eligibility. On re-assessment of the downloaded papers, 14 were excluded as not fitting the eligibility criteria, leaving a final 7 studies to be included in the meta-analysis.

The 7 studies identified are listed in Table 1. The results were analysed using the random effect model, this also took into account separate weightings of each study.

The results of the systematic review are presented in Figure 1, the PRISMA flow diagram. Table 1 shows the 7 studies[23, 28-36] included in final meta-analysis, with the means and standard deviations of the baseline OHIP-EDENT scores. Figure 2 shows the forest plot for included studies using random effects model for each study. The analysis rendered a baseline OHIP-EDENT score of 28.63 with 95% confidence interval between 21.93 and 35.34.

Table 1. List of studies included in final meta-analysis including each paper's sample size, reported mean and standard deviation.

Study ID	Title and author	Year	Study design	Sample size	Baseline mean OHIP EDENT score	Standard deviation
3	Association between patient satisfaction with complete dentures and oral health related quality of life: two year longitudinal assessment. Stober T, Danner D, Lehman F.	2010	Cohort study	22	22.90	2.20
4	A structured equation modelrelating oral condition, denture quality, chewing ability, satisfaction and oral health related quality of life in complete denture wearers. Yamaga E, Sato Y, Minakuchi S.	2013	Cohort study	166	26.40	14.40
5	Influence of minimally invasive implan-retained overdenture on patients' quality of life: a randomized clinical trial. Jofre J, Castiglioni X, Lobos CA.	2012	RCT	30	36.60	8.20
7	Association between self-assessment of complete dentures and oral health-related quality of life. Komagamine Y, Kanazawa M, Kaiba Y.	2012	Cohort study	93	26.27	14.40
9	Oral health related quality of life in hospitalised stroke patients. Schimmel M, Leemann B, Christou P.	2011	Cohort study	31	18.80	15.50
10	The association of responsivness in oral and geaneral health related quality of life with patients' satisfaction of new complete dentures. Kuo HC, Kuo YS, Lee IC.	2012	Cohort study	224	23.70	13.46
11**	A randomised controlled trail of complete denture impression materials. Hyde TP, Craddock HL, Gray JC et al	2014	RCT	81	45.20	17.28

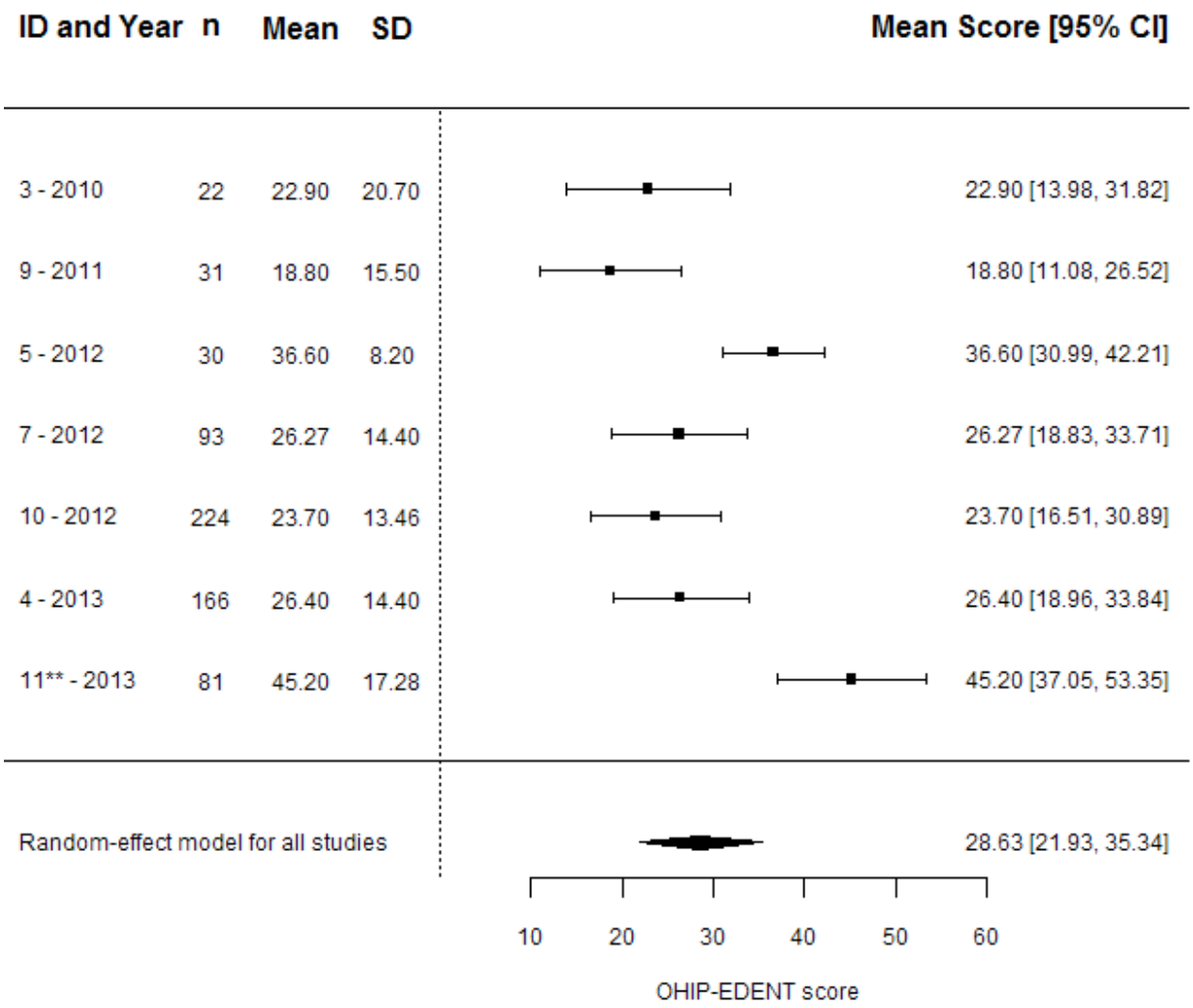

Figure 2: Forest plot for included studies showing their sample size, standard deviation and reported mean which underwent meta-analysis using random effects model for each study to produce baseline OHIP-EDENT score of 28.63 with 95% confidence interval between 21.93 and 35.34.

DISCUSSION

The studies included in the final meta-analysis had participants within a very similar age range. They reported a mean age of participants ranging from 66.3 years old to 74.6 years old (Study 5 and Study 10 did not report a mean age but did report age ranges in line with the other studies).

Reported ranges for standard deviation of each study were relatively broad, perhaps indicating the personal subjectivity involved in assessing OHRQoL. The extent of the variance in the data was not analysed.[35]

With the exception of Study 9, all participants included in the studies were actively seeking treatment. It can be hypothesised that individuals actively seeking treatment are more likely to experience decreased OHRQoL.

Study 9 had a cohort of participants which were different from participants in the other studies as their participants had suffered from hemi facial paresis which could have greatly impacted their perceived OHRQoL, however against expectation, this cohort of patients reported the lowest OHIP-EDENT baseline score.

Studies 3, 9 and 11 had all been conducted in Western Europe (Germany, Switzerland and the UK respectively). Studies 4, 7 and 10 were carried out in dental institutes across Asia (Japan, Japan and Taiwan respectively) and they reported very similar baseline OHIP-EDENT scores between 23.70 and 26.40. Study 5 was the only one carried out in Latin America (Chile). Cultural and regional differences may contribute to differences in OHRQoL. Although no direct analysis was possible, the results are indicative of the cross cultural validity of the OHIP-EDENT. The 7 studies were carried out in 5 different languages. Studies 3 and 9 used German questionnaires, studies 4 and 7 used Japanese questionnaires, and studies 5 & 10 used Spanish and Mandarin questionnaires respectively, with only study 11 using the original OHIP-EDENT questionnaire in English. The studies using Japanese,[36] Chinese,[37] German[38] and Spanish[39] OHIP-EDENT questionnaires all reported the validation of the questionnaire in their language. However, there remains a possibility of a difference in reported OHIP-EDENT scores due to language differences and lexical choice.

Study 3, 5 and 9 had relatively small sample size of participants, all less than 31, which meant inherently a suspected increase in standard error. This was particularly evident in paper 3, with the smallest sample size of 22 participants with a standard error of 4.41 calculated from the reported standard deviation and sample size.

One study in particular, study 10, contributed over a third of the entire sample size for the meta-analysis and this may have skewed the results. However, because of the larger sample size, study 10 also had the smallest standard error calculated as 0.90.

Only two of the included studies, study 5 and 11, were randomised clinical trials with the remainder being cohort studies. Since we are looking at baseline score (OHIP EDENT baseline), the study design should not affect the perceived OHRQoL of the participants prior to any treatment being provided. However, these studies (5 and 11) had the highest reported OHIP-EDENT baseline means , that is the worse quality of life and so arguably the greatest treatment need.

In study 9, the authors reported the investigators assisted the participants with completing the OHIP-EDENT questionnaires if required. There was no mention of how many participants received such assistance; this assistance raises the possibility of introducing potential investigator bias.

The final result for the baseline OHIP EDENT from the studies identified was 28.63 with 95% confidence interval 21.93-35.34. We have therefore rejected the null hypothesis and propose the alternative hypothesis that it was possible to derive a baseline OHIP-EDENT from the available literature via means of meta-analysis.

Many studies have been conducted to assess OHRQoL using OHIP-EDENT, this was evidenced by the number of studies included for full assessment against eligibility criteria (n = 21). However, before this study, no meta-analysis had been carried out to provide a 'normal' baseline across the studies. Notwithstanding the limitations detailed above, this analysis provides a baseline for future research into this area. It will allow researchers to make inferences about the relative oral health related quality of life at the baseline of their study for their particular trial populations.

CONCLUSION

Within the limitations of this study, a pre-operative baseline OHIP-EDENT has been established by meta-analysis of published papers. The analysis yielded a OHIP-EDENT baseline of 28.63 (95% CI between 21.93 and 35.34). This will facilitate the comparison of the initial OHRQoL of one study population to that found elsewhere in the published literature.

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